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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|-------------------------|-------------------------------|------------------|
| 10/501,353   | 07/14/2004  | Enrico Anthony Antonini | 1580 WO/US                    | 7589             |
| 7590 04/20/2007<br>Jeffrey S Boone<br>Mallinckrodt Inc<br>675 McDonnell Boulevard<br>PO Box 5840<br>St Louis, MO 63134 |             |                         | EXAMINER<br>AULAKH, CHARANJIT |                  |
|  |             |                         | ART UNIT<br>1625              | PAPER NUMBER     |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             |                         | MAIL DATE                     |                  |
| 3 MONTHS   |             |                         | 04/20/2007                    |                  |
|  |             |                         | DELIVERY MODE<br>PAPER        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary****Application No.**

10/501,353

**Applicant(s)**

ANTONINI, ENRICO ANTHONY

**Examiner**

Charanjit S. Aulakh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-163 is/are pending in the application.  
4a) Of the above claim(s) 44-67, 71-150 and 155-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43, 68-70 and 151-154 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/14/04, 11/30/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. According to paper filed on Feb. 1, 2007, the applicants have elected group I without traverse for further prosecution. Claims 44-67, 71-150 and 155-163 are withdrawn from further consideration as being directed to non-elected inventions.
2. Claims 1-43, 68-70 and 151-154 are now pending in the application.

### ***Specification***

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-43, 68-70 and 151-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oletta ( GB 890,614, cited on applicant's form 1449 ).

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Oletta discloses a process for preparing or separating alkaloids from crude extracts in an organic solvent, treating the extract with an aqueous solution of an acid, making the aqueous portion of the extract alkaline to precipitate the alkaloid and separating the alkaloid by chromatography and crystallizing from methanol ( see claim 7 and page 1, col. 2, lines 77-84 ). Oletta meets all the limitations except that Oletta does not mention separating morphine ( alkaloid ) and furthermore, does not describe the stationary phase media and mobile phase in detail. However, Oletta does mention using silica material as stationary media ( see page 1, col. 2, lines 77-84 ) and furthermore, the process of Oletta is generally applicable for separating any alkaloid from the crude extract. Therefore, one skilled in the art would have been motivated to use the process of Oletta for separating any alkaloid including morphine.

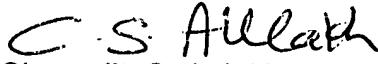
7. Claims 1-37, 68-70 and 151-154 are objected for containing non-elected subject matter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625